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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,946	03/11/2004	David B. Wiley	632898-042-C1	4846

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
10/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/797,946	WILEY ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 7/19/07.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed **7/19/07** presents remarks and arguments to the office action mailed **1/19/07**. Applicant's request for reconsideration of the rejection of claims in the last office action has been considered.

Applicant's arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of Claims:

Claims 1-25 are pending.

Claims 1, 6-10, 13, 15, 17-18, 21 and 23-24 have been amended.

Maintained Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 1, 3, 5-6, 9, 11-12 and 14 remain rejected under 35 U.S.C. 102(b) as being anticipated by Nissen et al. US 6,031,000.

Nissen et al disclose the current claims 1, 3, 6, 12 and 14 administering calcium 3-hydroxy-3-methylbutyrate (ca-HMB)(see col. 3 lines 62+) to increase the aerobic capacity of muscle of an animal, administering a dose (effective amount- see col. 3 lines 60+) of ca-HMB. Consequently, the reference anticipates the claimed invention defined in claims 1 and 5.

With regard to claim 3, the pharmaceutically carrier is (see col. 3 lines 55+), administering 10 g an equivalent to 1000 mg of ca-HMB (see col. 3 lines 65+) as in claim 6 in a solid dosage form recited in claim 9 (see col. 3 lines 55+) wherein the form is of a food product (see col. 6 lines 55+) as in the current claim 11.

Applicant's argument that the instant amended claims recites treating a subject with having a deficiency in calcium and or magnesium serum levels makes the rejection of record moot. Also, that Nissen fails to disclose either of the claim limitation.

In responses, this is found unpersuasive, because patients with AIDS do suffer from hypocalcaemia. This is well known in the art. For example as evident by Kuehn et al., Aids patient suffer from low calcium levels. See discussion section. With regard to the limitation a deficiency in calcium and/or magnesium serum levels, thereby elevating serum levels of calcium and/or magnesium is an inherent property. The Nissen teaches having blood samples prior and after the patient has been giving the claimed compound, see col. 10, lines 1-4.

Applicant's arguments have been fully considered but they are not persuasive. See reasons above and the rejection is maintained as in the last office action of record

II. Claims 1, 5-6 and 9 remain rejected under 35 U.S.C. 102(b) as being anticipated by Vukovich et al. American Soc. Nutr. Sci.

Vukovich et al disclose the current claim 1and 5 administeration of an effective amount of calcium 3-hydroxy-3-methylbutyrate to treat loss of muscle mass (see page 2049) a calcium deficiency as disclosed in the current claim 1. Consequently, the reference anticipates the claimed invention defined in claim 1.

As to claim 6 the reference discloses administering calcium 3-hydroxy-3-methylbutyrate at 250 mg (see page 2049 under study design) in a solid form-capsule as in current claim 9.

Applicant's argument that the composition of Vukovich never, teaches administration to address calcium and or magnesium deficiency is found unpersuasive. The reference teaches administration of Ca-HMB to young adults to increase gains in strength associated with loss of muscle mass, wherein blood samples are drawn before and after administration to analyze plasma level of ca-HMB. See page 2050, under blood collection analysis. Applicant's arguments have been fully considered but they are not persuasive. See reasons above and the rejection is maintained as in the last office action of record

III. Claims 1, 5-6, 7-9, 12 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/17678.

WO 94/17678 discloses the instant claims 1 and 12 administering 3-hydroxyl -3-methylbutyrate (see page 7), wherein the mineral supplement is calcium 3-hydroxyl -3-methylbutyrate as in claim 5 (at page 9) by administering at a level of 1000 mg (see page 9) as in claim 6. The reference also teaches various salts forms of the 3-hydroxyl -3-methylbutyrate, magnesium can be employed, therefore it will be obvious the teachings of claims 7 and 8.

The argument to this is the same as above. In response, the serum levels, thereby elevating serum levels of calcium and/or magnesium is an inherent property.

In response, the abstract clearly teaches enhancing the nutritional value of colustrum and first milk of a pregnant woman. Again Examiner has shown that the same compound as claimed is administered to pregnant mammals because bone loss occurs during pregnancy and during lactation, thus anticipated a condition associated with calcium and or magnesium.

Applicant's arguments have been fully considered but they are not persuasive. See reasons above and the rejection is maintained as in the last office action of record

Claim Rejections - 35 USC § 103

Applicant argues that the references fail to show prima facie obviousness because one of ordinary skill in the art would not have considered these references and would not have led to the present invention.

In response, one of ordinary skill in the art would have been motivated to combine the cited art because the cited art teach a method of treating calcium and or magnesium deficiencies for the same reasons given above.

Applicant's arguments have been fully considered but they are not persuasive. See reasons above and the rejection is maintained as in the last office action of record

Claims 1-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nissen et al. US 6,031,000 taken with Vukovich et al. American Soc. Nutr. Sci. and WO 94/17678 in view of www.naturalconnections.com (1998) as in the office action of record dated 4/19/06.

Maintained Double Patenting

Claims **1 - 25** remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 12-20, 26-33 and 37-39 of U.S. Patent Application No. **10667283**. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

Both sets of claims refer to treating a calcium and /or magnesium- in the current application (claims 1 - 25) and elevating blood serum levels (claims 1-6, 12-20, 26-33 and 37-39) in the copending application. The current application claims are obvious variation of the copending application claims.

Both applications recite using the same compositions and/or derivatives thereof. See current application claims 1 - 25 and copending application claims 1-6, 12-20, 26-

33 and 37-39. Elevating serum level is a characteristic property of the claimed compound. As evident by Nissen having blood samples prior and after the patient has been giving the claimed compound, see col. 10, lines 1-4 teaches checking the level of the compound in the serum.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
9/24/07

Ardin H. Marschel 9/30/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER